

REMARKS

Reconsideration and withdrawal of the restriction requirement and election of species are respectfully requested in view of the remarks herein.

The July 31, 2003 Office Action required restriction from among:

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| Group A | Claims 56-67, 70 and 71, drawn to a method for administering a peptide; and |
| Group II | Claims 68 and 69, drawn to a method for administering a peptide, wherein a screening step is used prior to the administering of the peptide. |

Applicants elect, with traverse, the claims of Group B, i.e. claims 68 and 69.

Additionally, the Office Action required the election of a single species for prosecution. The Office Action did not specify what type of species was to be elected. Applicants have assumed that the species in question was to be elected from one of the adjuvants set forth in claim 77, and accordingly select saponin, with traverse. Should Applicants be mistaken as to the election required, it is respectfully requested that the Office Action be withdrawn and a new Office Action issued which explicitly sets forth the species to be included in the election.

The MPEP lists two criteria for a proper restriction requirement. First, the invention must be independent or distinct. MPEP § 803. Second, searching the additional invention must constitute an undue burden on the examiner if restriction is not required. *Id.* The MPEP directs the examiner to search and examine an entire application “ [i]f the search and examination of an entire application can be made without serious burden, ... even though it includes claims to distinct or independent inventions.” *Id.*

It is respectfully submitted that the Office Action provides no showing that the claims of Groups A and B are distinct. In fact, after setting forth the two groups of claims, the Office Action fails to state anything that would support the restriction requirement.

It is again respectfully submitted that MPEP § 803 directs the examiner to search and examine an entire application “[i]f the search and examination of an entire application can be made without serious burden, ... even though it includes claims to distinct or independent inventions.” *Id.*

Again, it the Office Action provides no showing that search and examination of the claims of Groups A and B would be a serious burden. In fact, the Office Action neglects to provide a classification for the Groups. As it is a small number of claims in question, divided

into two Groups, with Group B containing only 2 claims, it is respectfully submitted that it would not be an undue burden to examine the claims of both Group A and Group B.

In view of the above, and considering that the Office Action provides no support whatsoever that restriction is required, reconsideration and withdrawal of the restriction requirement is respectfully requested.

Furthermore, the Examiner is respectfully requested to review M.P.E.P. §808.01(a), which states that "where there is no disclosure of relationship between species (*see* M.P.E.P. §806.04 (b)), they are independent inventions and election of one invention" is required. In view of M.P.E.P. §803, however, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate.

In the instant case, the Office Action fails to state what species requires election. Applicants have assumed that the election of species is directed towards the adjuvants of claim 77, and the comments herein are accordingly directed to the species of adjuvants in claim 77.

It is respectfully submitted there is a disclosure of relationship between the claimed species. Claim 77 recites 4 possible adjuvants for use in conjunction of the administering of a peptide. Consequently, there is a disclosed relationship between the adjuvants.

Furthermore, the Office Action has made no showing that searching the adjuvants of claim 77 would constitute an undue burden. Consequently, it is respectfully submitted that the requirement for an election of species is inappropriate.

In view of the above, reconsideration and withdrawal of the election of species requirement are requested.

In summary, enforcing the present restriction and election requirements would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially since it has been shown that the requisite showing of serious burden has not been made, and it has not been shown that the claims of Groups A and B constitute distinct inventions. Indeed, the search and examination of each Group would be likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner, especially as the claims of all

Groups have identical classifications. Furthermore, the election requirement has not been shown to be proper, especially since, *inter alia*: 1) the requisite showing of serious burden has not been made in the Office Action; and, 2) there are relationships among adjuvant species. All of the preceding, therefore, mitigate against restriction.

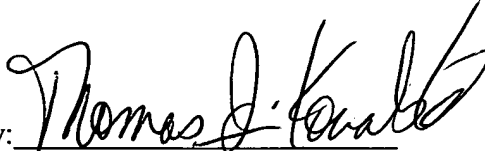
Consequently, reconsideration and withdrawal of the restriction and election of species requirement are respectfully requested.

CONCLUSION

In view of the amendments, and remarks herein, reconsideration and withdrawal of the restriction requirement and election of species is respectfully requested. Applicants respectfully request an early and favorable examination on the merits.

Respectfully submitted,

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